



Department of Medical Assistance Services
600 East Broad Street
Suite 1300
Richmond, VA 23219

<https://dmas.virginia.gov>

MEDICAID BULLETIN

Mandatory Medicaid Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials

Last Updated: 03/09/2022



Mandatory Medicaid Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials

The purpose of this bulletin is to inform providers that DMAS and all managed care organizations (MCOs) will cover routine patient costs furnished in connection with a member's participation in a qualifying clinical trial. Per guidance described in the Centers for Medicare and Medicaid Services (CMS) State Medicaid Director (SMD) letter [#21-005](#):

- Routine patient costs that must be covered for a beneficiary participating in a qualifying clinical trial are any item or service provided to the individual under the qualifying clinical trial, including any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial, to the extent that the provision of such items or services to the beneficiary would otherwise be covered outside the course of participation in the qualifying clinical trial under the state plan or waiver, including a demonstration project under section 1115 of the Act. Such routine services and costs also include any item or service required solely for the provision of the investigational item or service that is the subject of the qualifying clinical trial, including the administration of the investigational item or service.
- Routine patients costs do not include: any investigational item or service that is the subject of the qualifying clinical trial and is not otherwise covered outside of the clinical trial under the state plan, waiver, or demonstration project; and any item or service that is provided to the beneficiary solely to satisfy data collection and analysis for the qualifying clinical trial that is not used in the direct clinical management of the beneficiary and is not otherwise covered under the state plan, waiver, or demonstration project.

Providers should reference SMD #21-005 for additional, detailed information on which services are covered/not covered, definition of a qualifying clinical trial, and coverage determination requirements.

The effective date of coverage of these services is contingent upon the publication of a uniform provider attestation form – currently under development – developed for state use by the Secretary of Health and Human Services (HHS). Further guidance will be issued by DMAS after publication of the provider attestation form the HHS.



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PROVIDER CONTACT INFORMATION & RESOURCES	
Virginia Medicaid Web Portal Automated Response System (ARS) Member eligibility, claims status, payment status, service limits, service authorization status, and remittance advice.	www.virginiamedicaid.dmas.virginia.gov
Medicall (Audio Response System) Member eligibility, claims status, payment status, service limits, service authorization status, and remittance advice.	1-800-884-9730 or 1-800-772-9996
KEPRO Service authorization information for fee-for-service members.	https://dmas.kepro.com/
Provider Appeals DMAS launched an appeals portal in 2021. You can use this portal to file appeals and track the status of your appeals. Visit the website listed for appeal resources and to register for the portal.	https://www.dmas.virginia.gov/appeals/
Managed Care Programs Medallion 4.0, Commonwealth Coordinated Care Plus (CCC Plus), and Program of All-Inclusive Care for the Elderly (PACE). In order to be reimbursed for services provided to a managed care enrolled individual, providers must follow their respective contract with the managed care plan/PACE provider. The managed care plan may utilize different guidelines than those described for Medicaid fee-for-service individuals.	
Medallion 4.0	http://www.dmas.virginia.gov/#/med4
CCC Plus	http://www.dmas.virginia.gov/#/cccplus
PACE	http://www.dmas.virginia.gov/#/longtermprograms
Magellan Behavioral Health Behavioral Health Services Administrator, check eligibility, claim status, service limits, and service authorizations for fee-for-service members.	www.MagellanHealth.com/Provider For credentialing and behavioral health service information, visit: www.magellanoofvirginia.com , email: VAProviderQuestions@MagellanHealth.com , or Call: 1-800-424-4046
Provider HELPLINE Monday-Friday 8:00 a.m.-5:00 p.m. For provider use only, have Medicaid Provider ID Number available.	1-804-786-6273 1-800-552-8627



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Aetna Better Health of Virginia	www.aetnabetterhealth.com/Virginia 1-800-279-1878
Anthem HealthKeepers Plus	www.anthem.com/vamedicaid 1-800-901-0020
Molina Complete Care	1-800-424-4524 (CCC+) 1-800-424-4518 (M4)
Optima Family Care	1-800-881-2166 www.optimahealth.com/medicaid
United Healthcare	www.Uhcommunityplan.com/VA and www.myuhc.com/communityplan 1-844-752-9434, TTY 711
Virginia Premier	1-800-727-7536 (TTY: 711), www.virginiapremier.com